BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

In the Matter of Toxic Substances Control Act

Petition for Rulemaking under Section 21 of the Toxic Substances Control Act

I. Introduction

In adopting the Toxic Substances Contro1 Act of 1976 ("TSCA" or the "Act"),[1] Congress declared it US. policy that (1) "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment"[ii] and (2) "adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment."[iii] Toward those ends, the Act directs the Environmental Protection Agency ("EPA" or the "Agency") to promptly compile and publish a list of all chemical substances manufactured or processed in the U.S. in high volumes."[iv] It also requires persons who manufacture, process or distribute chemical substances or mixtures to (1) keep records of significant adverse reactions to health or the enviromnent caused by a chemical [v] and (2) notify the EPA if they have information indicating that a chemical presents a substantial risk of injury to health or the environment.[vi] Further, it empowers the Agency to require such persons to (1) record and report information concerning the health and environmental effects of chemicals [vii] and (2) submit health or safety studies concerning particular chemicals that are known or available to them.[viii] Finally, it authorizes the Agency to require testing of particular chemicals to assess their toxicity,[ix] and in appropriate cases to regulate their use.[x]

In 1997, some twenty years after TSCA was enacted, the Environmental Defense Fund issued a report[xi] charging that basic toxicity data could not be found for 75% of a random sample of some 2800 high production volume industrial chemicals on the EPA published list. The EDF report generated wide attention and criticism of the EPA. [xii]

Spurred to action, the EPA soon issued its own report.[xiii] The EPA report detailed the extent to which it appeared data was missing and concluded, *inter alia*, that "Chemical companies need to do more to deal with this problem."[xiv] Within the month, in an Earth Day speech in April 1998, Vice President Gore called on government, industry, and the environmental community to develop a plan to rapidly fill the data gaps.[xv]

Spurred now by the Vice President into a headlong gallop, the EPA in October, 1998 announced the launch of a massive, expedited chemical testing program. The crash program was called "The High Production Volume Voluntary Challenge Program."[xvi] It contemplated the testing of approximately 2,800 HPV chemicals by the year 2004 because for those chemicals, "basic testing data are not available or not publicly accessible."[xviii] The Program contemplated, of course, that the testing be done by chemical companies,[xviii] and the EPA solicited the voluntary participation[xix] of chemical companies. Many companies signed up, and the testing industry, anticipating a profitable windfall, geared up for wholesale testing.[xxi]

Fortunately, the Agency, on sober reflection, has had second and better thoughts. Last month the EPA announced that as a result of concerns raised by animal protection organizations and the general public, it has agreed to re-structure the

Challenge Program.[xxii] Rather than hastily undertake an expensive and time-consuming program of *de novo* testing of chemicals on animals,[xxiii] the Agency sensibly decided to put the cart behind the horse. Under the re-structured program, the EPA first will concentrate on (1) finding and evaluating all existing data on the toxicity of HPV chemicals, and (2) improving the testing process by developing alternative testing methods that do not use animals as test subjects.[xxiv]

This Petition addresses the first prong of the restructured Challenge Program, i.e., the Agency's efforts to make more and better use of existing data.

The Agency already has agreed, as one way of making more existing data available to the public, to grant amnesty with respect to belated reporting of information covered by Sec. 8(e) of the Act by participants in the Challenge Program.[xxv] Disclosure of previously withheld Sec. 8(e) information clearly will enlarge the public pool of data, and that is all to the good.[xxvi]

That section of the Act, however, covers only "information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment." There is, of course, another and equally probative category of data not covered by Section 8(e): information that reasonably supports the conclusion that a chemical substance or mixture presents no substantial risk of injury.

The Agency can add such "exculpatory" data concerning HPV chemicals to the pool of publicly available information by issuing rules requiring maintenance of health and environment records and reports under Sec. 8(a) and disclosure of existing health and environment studies under Sec. 8(d). The Act specifically authorizes the Agency to do that. This Petition asks the Agency to use its authority

The case for rules requiring records and reports of existing data and disclosure of health studies is compelling. Such rules are by far the quickest and least expensive way to make available to the public a major category of information bearing on the risk to health and the environment posed by HPV chemicals. To get such information is the declared purpose of the Challenge Program and the Act. The rules proposed here by Petitioner are nothing more or less than logical and necessary components of the EPA's efforts to fill the gaps in public knowledge concerning the risks to health and the environment from chemicals.

II. Information About the Petitioners

People for the Ethical Treatment of Animals ("PETA")
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Norfolk VA 23510
For further information, contact Jessica Sandler, Federal Agency Liaison
(757) 622-7382, Ext. 304

PETA, founded in 1980, is a non-profit corporation qualified under I.R.C. Sec 501(c)(3). Headquartered in Norfolk, Virginia, it has more than 600,000 individual members and is the largest animal rights organization in the world. PETA is dedicated to establishing and protecting the rights of all animals.

The Physicians Committee for Responsible Medicine ("PCRM")
5100 Wisconsin Avenue, N.W.
Suite 404
Washington, D.C. 20016
For further information, contact Mindy S. Kursban, PCRM Staff Counsel
(202) 686-2210, Ext. 307

PCRM, founded in 1985, is a non-profit public interest organization qualified under I R C. Sec. 501(c)(3). Headquartered in Washington, D.C., it has approximately 5000 physician members and approximately 100,000 lay members. PCRM encourages higher standards for ethics and effectiveness in medical research.

Doris Day Animal League ("DDAL")

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Washington, DC 20002
For further information, contact Sara Amundson, Deputy Director
(202) 546-176l, Ext. 27

DDAL, founded in l987, is a non-profit corporation qualified under I.RC. Sec. 50l(c)(4). Headquartered in Washington, DC, it has more than 300,000 individual members and supporters. The DDAL is committed to statutory and regulatory changes to integrate non-animal testing methods into federal and state statutes and regulations.

International Marine Mammal Project of Earth Island Institute
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Suite 28
San Francisco, CA 94133
For further information, contact Marc Berman, Program Associate
(415)788-3666,Ext. 146

Earth Island Institute, founded in 1982, is a non-profit corporation qualified under I.RC. Sec. 501(c)(3). Headquartered in San Francisco, CA, it has more than 100,000 individual members and supporters. Earth Island Institute combines innovative educational and grassroots campaigns dedicated to the conservation, preservation, and restoration of the global environment.

National Anti-Vivisection Society ("NAVS")
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For further information, contact Marcia Kramer, Director of Legal and Legislative Programs, (312)427-6065

NAVS, founded in 1929, is a non-profit corporation qualified under IRC. Sec. 501(c)(3). Headquartered in Chicago, IL, it has more than 50,000 individual members and supporters. NAVS is dedicated to ending the exploitation of animals used in medical research, education, and product testing.

III. Description of the Relief Requested

Subsections (1) and (2) of Sec 8(a) of the Act, taken together, provide in substance (*inter alia*) that the Administrator may (1) promulgate reasonable rules requiring that manufacturers and processors of chemical substances or mixtures maintain such records as the Administrator may reasonably require[xxvii] and (2) submit reports of "[a]ll existing data concerning the environmental and health effects of. . . [any] substance or mixture" as to which records are required to the extent such data is known to the manufacturer or processor or reasonably ascertainable.[xxviii]

Subsections (1) and (2) of Sec. 8(d) of the Act, taken together, provide in substance that the Administrator, when necessary for the effective administration of the Act, shall promulgate rules under which the Administrator shall require any person who manufactures, processes or distributes any chemical substance or mixture to submit, with respect to any such chemical, (1) lists of health and safety studies (a) conducted or initiated by or for such person at any time, (b) known to such person, or (c) reasonably ascertainable by such person[xxix] and (2) copies of any such listed study or study otherwise known to such person.[xxx] PETA petitions the Administrator of the Agency under Sec. 21 of the Act to initiate proceedings with respect to all chemical substances or mixtures included on the HPV Challenge Program List promulgated pursuant to Sec. 8(b) of the Act, as updated through the date of initiation of the proceedings) (1) for the issuance of a Preliminary Assessment Information Rule under Sec. 8(a) requiring all persons who manufactured or imported any covered substance or mixture to submit a Preliminary Assessment Information Manufacturer's Report [xxxi] with respect to each such substance or mixture, and (2) for the issuance of a Health and Safety Data Reporting Rule under Sec 8(d) requiring all persons who manufactured, imported or processed any covered substance or mixture to report

unpublished health and safety data in accordance with the guidelines provided in the Federal Register of September 15, l986.[xxxii] Such rules should neither be limited to participants in the Challenge Program nor exclude substances or mixtures as to which a participant has enrolled in the Program.

IV. Description of the Problem

The underlying problem, as described in the introduction to this Petition, is that there are gaps in the public information concerning the risk to health and the environment that may or may not be posed by high production volume chemicals.

The immediate problem is how best to implement the HPV Challenge Program. The steps announced by the Agency on October 14 go far toward solving that problem, but more can and should be done. It is known that there is much existing but not yet public information, a substantial body of which reveals that some chemicals are not a threat to health or the environment. [xxxiii] In order that industry, the EPA and the environmental movement may concentrate their energies on conducting and interpreting such additional testing as eventually may prove necessary, it is important now to eliminate from the field of concern those chemicals that already have been shown to be safe.

A part of the immediate problem has in the voluntary nature of the HPV Challenge Program. Past efforts by the EPA to fulfill its mandate under the Act to develop data with respect to the effect of chemical substances and mixtures on health and the environment by encouraging voluntary submission of data have failed to do the job. For example, the Voluntary Information Submission Policy adopted and promoted by the TSCA Interagency Testing Committee ("ITC") in collaboration with the Office of Pollution Prevention and Toxics, even when supplemented with the ITC's "VISION" system for electronic submissions, has been ineffective. [xxxiv] In its Spring 1998 semi-annual report to the EPA, [xxxv] the ITC specifically refrained from requesting the EPA to promulgate a Sec. 8(d) rule for any of the chemicals as to which the ITC recommended testing, noting that it was encouraging producers, importers, processors and users of the subject chemicals to use VISION to make voluntary submissions and establish a dialogue with the ITC to discuss needed data. Six months later, when the ITC issued its Fall, 1998 Report, [xxxvi] the ITC was forced to face the failure of voluntary reporting and ask the EPA to issue an 8(d) rule. The EPA issued a proposed rule in June 1999, [xxxvii] shortly after the ITC submitted its Spring, 1999 Report. [xxxviii]

V. Benefits to be Derived from Requested Rule Under Sec. 8

The proposed rule will quickly and economically produce much information that could allow the EPA to eliminate some chemicals from the field of concern so that future testing and evaluation efforts can be concentrated on chemicals that may not be safe. Reliance on voluntary submission of data bearing on the risk of injury to health and the environment from chemicals has not been adequate. Thus the proposed rules mandating such submission of data are necessary for the effective administration of the Act.

The Agency itself has stressed the utility of Sec. 8(a) rules (commonly called "preliminary assessment information rules", or "PAIRs") and Sec. 8(d) rules (commonly called "health and safety study" rules, or "HaSS" rules). In giving to the Office of Management and Budget notice as required by the Paperwork Reduction Act [xxxix] of proposed Sec. 8(d) rules, the EPA said that such "information collection requests" are necessary to effectuate the purposes of the Act because the Agency "uses this information to construct a complete picture of the known effects of the chemicals in question, leading to determinations by EPA of whether additional testing of the chemicals is required. The information enables EPA to base its testing decisions on the most complete information available and to avoid demands for testing that may be duplicative. EPA will use information obtained via this collection to support its investigation of the risks posed by chemicals and, in particular, to support its decisions on whether to require industry to test chemicals under section 4 of TSCA" [xl] (emphasis

added)

VI. Conclusion

For the reasons stated, it is incumbent on the Agency to issue the proposed rules.

Respectfully submitted,

/s/
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EndNotes

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[i] 15 USC 2601, et seq. Congress enacted the law after five years of public hearings and debate on a legislative proposal developed by the President's Council on Environmental Quality in 1971. That proposal was made in reaction to a growing public realization that some chemicals present a risk to health and the environment. See generally The Layman's Guide to the Toxic Substances Control Act, EPA 5601/1-87-011 (June 1987)

[ii] 15 USC 2602(b)(l).

[iii] 15 USC 2602(b)(2)

[iv] 15 USC 2607(b) The published list excludes substances manufactured or processed in small quantities (as defined by the Administrator) for specified limited purposes. The Administrator has defined small quantities as less than 1 million pounds per year. All other substances common1y are called "high production volume" chemicals

[v] 15 USC 2607(c).

[vi] 15 USC 2607(e)

[vii] 15 USC 2607(a).

[viii] 15 USC 2607(d).

[ix] 15 USC 2603.

[x] 15 USC 2605.

[xi] D Roe, et al., Toxic Ignorance: The Continuing Absence of Basic Health Testing for Top-Selling Chemicals in the United States (New York: Environmental Defense Fund. 1997)

[xii] See, e.g. P. Montague, The Toxic Substances Control Act (Rachel's Environment & Health Weekly No.564, September 18, 1997).

[xiii] Chemical Hazard Data Availability Study: 1998 Baseline of Hazard Information that is Readily Available to the Public EPA Office of Pollution Prevention and Toxics (April 1998)

[xiv] Summary of Chemical Hazard Data Availability Study, EPA. The Act puts the burden of developing toxicity data on chemical companies: "adequate data should be

developed with respect to the effect of chemical substances and mixtures on health and the environment and the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures." 15 USC 2601(b)(1)

[xv] See Chemical Right to Know Imitative statement on EPA, Office of Pollution Prevention and Toxics Internet Web Page (as last revised October 27,1999)

[xvi] Joint Announcement of a Cooperative Program for High Production Volume of U S Industrial Chemicals issued by the EPA on October 9, 1998, jointly with the Chemical Manufacturers Association and the Environmental Defense Fund. See also Principles of Participation in the HPV Challenge Program, pamphlet issued by the EPA.

[xvii] Voluntary Participation in the HPV Challenge Program, EPA Chemical Right to Know Fact Sheet Series (EPA 745-F-98-002b), page 1, paragraph 1.

[xxvii] See endnote xiv, *supra*.

[xix] Voluntary participation was encouraged by the Agency's agreement not to require testing of chemicals that companies voluntarily agreed to test under the Challenge Program. See concluding paragraph 7 of Joint Announcement cited in endnote xvi, *supra*.

[xx] Letter of October 9, 1998 to Chief Executive Officers of 900 chemical companies accounting for most of U.S. manufacture and import of HPV chemicals from Carol M. Browner, EPA Administrator.

[xxi] Before announcing the HPV Challenge Program, the EPA estimated, probably conservatively, that it would cost some $427 million just to perform the basic screening needed to fill the apparent gaps in public information concerning the toxic effects of the 2,800 chemicals. See Summary of Chemical Hazard Data Availability Study, EPA pamphlet.

[xxii] Letter of October 14, 1999 to participants in the Program from Susan H. Wayland, EPA Deputy Assistant Administrator for Office of Pollution Prevention and Toxics.

[xxiii] Estimates were that the testing program would requirement experiments on and killing of 1,300,000 laboratory animals.

[xxiv] CITE (to supporting authority that animal test not helpful).

[xxv] Failure to notify the EPA of Sec 8(e) information (indicating risk from chemicals to health or the environment) is subject to civil and criminal penalties. 15 USC 2614 and 2615.

[xxvi] Arguably it would better if amnesty were not limited to participants in the Challenge Program. The primary objective of the amnesty is to make public all information indicating substantial risk to health and the environment from HPV chemicals. Punishment of the recalcitrant, albeit a deterrent to future failures to report, should be secondary to the immediate goal of getting the existing data out in the open.

[xxvii] 15 USC 2607(a)(1)(A)

[xxviii] 15 USC 2607(a)(2)(E).

[xxix] 15 USC 2607(d)(1).

[xxx] 15 USC 2607(d)(2).

[xxxi] EPA Form 77l0-35.

[xxxii] 51 FR 32720.

[xxxiii] CITE (to supporting authority as to existence of exculpatory data).

[xxxiv] Bureau of National Affairs, Inc., Report on Chemical Safety Daily Environment No 106, June 3, 1999), quoting ITC Director Dr. John D. Walker.

[xxxv] Forty-Second Report of TSCA Interagency Testing Committee to the Administrator. EPA (May 1998).

[xxxvi] Forty-Third Report of TSCA Interagency Testing Committee to the Administrator, EPA (November 1998). [xxxvii] Federal Register June 9,1999 (Volume 64, Number 110). As yet no final Sec. 8(d) rule has been promulgated. Indeed, no rules under Sec. 8(d) have been promulgated since October 29, 1996.

[xxxviii] Fourth-Fourth Report of TSCA Interagency Testing Committee to the Administrator, EPA (May 1999).

[xxxix] 44 USC 3501 et seq.

[xi] See Notice in Federal Register, January 14,1999 Vol. 64, Number 9) concerning Toxic Chemicals: Agency Information Collection Activities.

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Endnotes

[i] 15 USC 2601, *et seq*. Congress enacted the law after five years of public hearings and debate on a legislative proposal developed by the President's Council on Environmental Quality in 1971. That proposal was made in reaction to a growing public realization that some chemicals present a risk to health and the environment. See generally The Layman's Guide to the Toxic Substances Control Act, EPA 5601/1-87-011 (June 1987).

[ii] 15 USC 2602(b)(1).

[iii] 15 USC 2602(b)(2).

[iv] 15 USC 2607(b). The published list excludes substances manufactured or processed in small quantities (as defined by the Administrator) for specified limited purposes. The Administrator has defined small quantities as less than 1 million pounds per year. All other substances commonly are called "high production volume" chemicals.

[v] 15 USC 2607(c).

[vi] 15 USC 2607(e)

[vii] 15 USC 2607(a).

[viii] 15 USC 2607(d).

[ix] 15 USC 2603.

[x] 15 USC 2605.

[xi] D. Roe, *et al*., Toxic Ignorance: The Continuing Absence of Basic Health Testing for Top-Selling Chemicals in the United States (New York: Environmental Defense Fund, 1997).

[xii] See, e.g., P. Montague, The Toxic Substances Control Act (*Rachel's Environment & Health* Weekly, No. 564, September 18, 1997).

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[xv] See Chemical Right to Know Initiative statement on EPA, Office of Pollution Prevention and Toxics Internet Web Page (as last revised October 27, 1999)

[xvi] Joint Announcement of a Cooperative Program for High Production Volume of U.S. Industrial Chemicals, issued by the EPA on October 9, 1998, jointly with the Chemical Manufacturers Association and the Environmental Defense Fund. See also Principles of Participation in the HPV Challenge Program, pamphlet issued by the EPA.

[xvii] Voluntary Participation in the HPV Challenge Program, EPA Chemical Right to Know Fact Sheet Series (EPA 745-F-98-002b), page 1, paragraph 1.

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[xxiii] Estimates were that the testing program would requirement experiments on and killing of 1,300,000 laboratory animals.

[xxiv] B. Ekwall, et al., MEIC Evaluation of Acute Systemic Toxicity: Part IV The Prediction of Human Toxicity by Rodent LD50 Values and Results From 61 *In Vitro* Methods, (*Alternatives to Laboratory Animals*, v. 26, pp. 617-658, 1998).

[xxv] Failure to notify the EPA of Sec. 8(e) information (indicating risk from chemicals to health or the environment) is subject to civil and criminal penalties. 15 USC 2614 and 2615.

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[xxvii] 15 USC 2607(a)(1)(A).

[xxviii] 15 USC 2607(a)(2)(E).

[xxix] 15 USC 2607(d)(1).

[xxx] 15 USC 2607(d)(2).

[xxxi] EPA Form 7710-35.

[xxxii] 51 FR 32720.

[xxxiii] William Sanders, Director, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Testimony Before the House Science Subcommittee on Energy and Environment (17 June 1999). During his testimony, Dr. Sanders stated, "EPA believes that substantial data on HPV chemicals may already exist in corporate files across America. This is due in part to the fact that many studies with negative results do not end up being published." See also: Chemical Manufacturers Association, Public Availability of SIDS-Related Testing Data for U.S. High Production Volume Chemicals (12 June 1998, pp. 38-39); Andrea Foster, Scope of Testing Narrows for HPV Chemicals (*Chemical Week*, 12 August 1999, p. 30); Steve Toloken, Public to Gain Access to Chemicals Data (*Plastics News*, 26 April 1999, p. 23); Peter Fairley, EDF Puts Producers on the Spot Over Untested High-Volume Chemicals (*Chemical Week*, 6 August 1997, p. 9).

[xxxiv] Bureau of National Affairs, Inc., Report on Chemical Safety (*Daily Environment* No. 106, June 3, 1999), quoting ITC Director Dr. John D. Walker.

[xxxv] Forty-Second Report of TSCA Interagency Testing Committee to the Administrator, EPA (May 1998).

[xxxvi] Forty-Third Report of TSCA Interagency Testing Committee to the Administrator, EPA (November 1998).

[xxxvii] Federal Register: June 9, 1999 (Volume 64, Number 110). As yet no final Sec. 8(d) rule has been promulgated. Indeed, no rules under Sec. 8(d) have been promulgated since October 29, 1996.

[xxxviii] Forty-Fourth Report of TSCA Interagency Testing Committee to the Administrator, EPA (May 1999).

[xxxix] 44 USC 3501 *et seq*.

[xl] See Notice in Federal Register, January 14, 1999 (Vol. 64, Number 9) concerning Toxic Chemicals; Agency Information Collection Activities.